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| 10/580,856 | 11/21/2006 | Jacques Defaye | 0508-1163 | 5988 |
| 466 | 7590 | 09/14/2009 | | |
| YOUNG & THOMPSON | | | EXAMINER | |
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| Suite 500 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/580,856 | DEFAYE ET AL. |
| | Examiner | Art Unit |
| | Jonathan S. Lau | 1623 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 02 July 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 21-43 is/are pending in the application.
 4a) Of the above claim(s) 21-34, 38, 40 and 42 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 35-37, 39, 41 and 43 is/are rejected.
 7) Claim(s) 35-37, 39, 41 and 43 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02 July 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, 02 July 2009, in which claims 21 and 36 are amended to change the scope and breadth of the claim.

The declaration of Jacques Defaye (inventor), submitted by Applicants on 02 July 2009 under 37 CFR § 1.132, is acknowledged and will be further discussed below.

This application is the national stage entry of PCT/FR04/02998, filed 24 Nov 2004; and claims benefit of foreign priority document FRANCE 0323873, filed 26 Nov 2003. An English language translation of this foreign priority document is of record.

Claims 21-43 are pending in the current application. Claims 21-34, 38, 40 and 42, drawn to non-elected inventions, are withdrawn. Claims 35-37, 39, 41 and 43 are examined on the merits herein.

Election/Restrictions

The invention of Group IV, claim(s) 35-37(in part), 39 (in part), 41 (in part) and 43 (in part), drawn to pharmaceutical composition comprising a complex of a pharmacologically active agent and a cyclodextrin dimer corresponding to the general formula (I) not containing a biological recognition element, is rejoined. The invention of Group IV is related to the previously elected invention of Group III as intermediate and final product with and shares the same utility as an inclusion complex of a pharmacologically active agent and a cyclodextrin dimer.

The Election of Species requirement detailed in the Office Action mailed 13 Feb 2008 is withdrawn.

Objections Withdrawn

Objection to claims 35-37, 39, 41 and 43 because claims 35-37, 39, 41 and 43 recite within each claim multiple distinct inventions of both Group III and Group IV has been withdrawn in view of the rejoined of Group IV detailed above.

This objection has been **withdrawn**.

Rejections Withdrawn

Applicant's Amendment and Remarks, filed 02 July 2009, with respect to claims 35-37, 39, 41 and 43 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been fully considered and is persuasive, as Applicant's remarks are persuasive with regards to "R³ representing a substituent allowing hydrolysis of the carbamate group in order to release the amine function" that in this specific context in view of the provided partial structure and the level of skill in the art the function of this R³ group is predictable and sufficient to describe the group, and claim 21 as amended describes specific substituents on the aromatic ring and biological recognition elements.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 02 July 2009, with respect to claim 36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as amended claim 36 does not recite the relative term "sufficiently large size".

This rejection has been **withdrawn**.

Applicant's Remarks, filed 02 July 2009, and the declaration of Jacques Defaye (inventor), submitted by Applicants on 02 July 2009 under 37 CFR § 1.132 with respect to claims 35-37 rejected under 35 U.S.C. 103(a) as being unpatentable over Ortiz-Mellet et al. (Chem. Eur. J. 2002, 8(9), p1982-1990, of record) in view of Kotter et al. (J. Chem.

Soc., Perkin Trans. 1, 1998, p2193-2200, of record) has been fully considered and is persuasive, as Applicant's remarks and the declaration of Jacques Defaye (inventor) under 37 CFR § 1.132 that the teaching of Ortiz-Mellet et al. provides guidance for the linker arms length but that this the spacer arm is separate from the branching element, that the teaching of Kotter et al. to link a thiourea function using tris(2-aminoethyl)amine discourages the use, and that both Ortiz-Mellet et al. and Kotter et al. suggest thiourea linkers are not the best linkers, plus the teaching that Kotter et al. is to a trivalent branching element having C3 symmetry and neither Ortiz-Mellet et al. nor Kotter et al. describe how to selectively functionalize the branching element with a reasonable expectation of success is persuasive as the combination of all these factors rebut the *prima facie* case of obviousness due to a lack of guidance to combine these elements with a reasonable expectation of success.

This rejection has been **withdrawn**.

Applicant's Remarks, filed 02 July 2009, and the declaration of Jacques Defaye (inventor), submitted by Applicants on 02 July 2009 under 37 CFR § 1.132 with respect to claims 39, 41 and 43 rejected under 35 U.S.C. 103(a) as being unpatentable over Ortiz-Mellet et al. (Chem. Eur. J. 2002, 8(9), p1982-1990, of record) in view of Kotter et al. (J. Chem. Soc., Perkin Trans. 1, 1998, p2193-2200, of record) as applied to claims 35-37, and further in view of Hamada et al. (US Patent 5,684,169, issued 04 Nov 1997, of record) has been fully considered and is persuasive, as Applicant's remarks and the declaration of Jacques Defaye (inventor) under 37 CFR § 1.132 are persuasive

regarding Ortiz-Mellet et al. in view of Kotter et al. as detailed above and the teaching of Hamada et al. does not remedy the teachings of Ortiz-Mellet et al. in view of Kotter et al. regarding Applicant's remarks and the declaration of Jacques Defaye (inventor) under 37 CFR § 1.132.

This rejection has been **withdrawn**.

Claim Objections

Claims 35-37, 39, 41 and 43 are objected to because of the following informalities: Claims 35-37, 39, 41 and 43 depend from withdrawn claim 21. 37 CFR 1.75(a) provides "The specification must conclude with a claim particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention or discovery." As the claim 21 is withdrawn, the dependent claims 35-37, 39, 41 and 43 do not particularly pointing out and distinctly claim the subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-37, 39, 41 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35-37, 39, 41 and 43 depend from claim 21 and incorporate all limitations therein.

Claim 21 recites Y represents an amide group of formula -NH-CO-(CH₂)_q-NR₁- or a cysteaminyl group of formula -S-(CH₂)-NR₁- at page 3, lines 1-6. These terms render the claim indefinite because the connectivity of these groups is unclear. For example, the cysteaminyl group may be attached to the cyclodextrin ring via a thioether bond at the S or via an amine bond at the NR₁. The amide group may be attached to the cyclodextrin ring via an amide bond at the NH-CO- or via an amine bond at the NR₁. Therefore each of these groups may be interpreted as two contrary structures having functionally different connectivity, rendering the claim indefinite.

Claim 21 recites R is a biological recognition element selected from "amino acid derivative" at page 4, line 18. The term amino acid derivative encompasses any compound that is theoretically derivable from an amino acid. One of ordinary skill in the art would not be readily apprised of the metes and bounds of the claim because it is unclear what structural features of amino acid derivatives are required to function as biological recognition elements.

Claim 21 recites "or also a fluorescent or radioactive visualization or detection probe" at page 4, lines 21-22. Claims 35-37, 39, 41 and 43 depend from claim 21 and incorporate all limitations therein. This term renders the claim indefinite because it is unclear if the term "also" requires that the probe be present in addition to a biological recognition element or if the R group also alternatively represents said probe. Further, the language renders it unclear if said "detection probe" is meant to be a fluorescent or

radioactive detection probe or if the terms is interpreted as "a fluorescent probe or radioactive visualization probe or detection probe".

Allowable Subject Matter

Claims 35-37, 39, 41 and 43 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

The closest prior art is Ortiz-Mellet et al. (Chem. Eur. J. 2002, 8(9), p1982-1990, of record) in view of Kotter et al. (J. Chem. Soc., Perkin Trans. 1, 1998, p2193-2200, of record).

Applicant's Remarks, filed 02 July 2009, and the declaration of Jacques Defaye (inventor), submitted by Applicants on 02 July 2009 under 37 CFR § 1.132 with respect to claims 35-37 rejected under 35 U.S.C. 103(a) as being unpatentable over Ortiz-Mellet et al. (Chem. Eur. J. 2002, 8(9), p1982-1990, of record) in view of Kotter et al. (J. Chem. Soc., Perkin Trans. 1, 1998, p2193-2200, of record) has been fully considered and is persuasive, as detailed above.

Moser et al. (US Patent 6,642,214, issued 4 Nov 2003, cited in PTO-892) teaches a cyclodextrin oligomer connected through a spacer for the encapsulation of an active pharmaceutical substance (abstract and figure 6). Moser teaches the spacer is a

rigid structural element (column 1, lines 60-70) and discloses preferred embodiments di-
β-CD(--NH--(C._{sub.8} H._{sub.16})--NH--); di-β-CD(terephthaliamide); di-β-CD(--
NHCO(trimesyl)CONH--); di-β-CD(--NH--(C._{sub.3} H._{sub.6})--NHCO--(C._{sub.3} H._{sub.6})--
CONH--(C._{sub.3} H._{sub.6})--NH--); di-β-CD(--NH--(C._{sub.2} H._{sub.4})--
NHCO(trimesyl)CONH--(C._{sub.2} H._{sub.4})--NH--); di-β-CD(--NH--(C._{sub.2} H._{sub.4})--SH--
-[6- α -CD-6]--SH--(C._{sub.2} H._{sub.4})--NH--); di-β-CD(--NH--(C._{sub.4} H._{sub.8})--NHCO--
(C._{sub.3} H._{sub.6})--COHN--(C._{sub.4} H._{sub.8})--NH--); di-beta-CD(--NH--(C._{sub.2}
H._{sub.4})--SH-[6-(β,γ -CD-6]--SH--(C._{sub.2} H._{sub.4})--NH--); or di-β-CD(--NH--(C._{sub.3}
H._{sub.6})--NHCO(trimesyl)COHN--(C._{sub.3} H._{sub.6})--NH--) (column 2, lines 10-30).

Moser et al. does not teach a cyclodextrin oligomer according to instant formula (I).

The instant invention would not have been obvious to one of ordinary skill in the art at the time of the invention because Moser et al. teaches the spaced to be a rigid structural element of aliphatic units or aromatic units. (column 4, lines 55-70). Therefore one of one of ordinary skill in the art would not be motivated to modify Moser et al. to arrive at the cyclodextrin oligomer according to instant formula (I).

Conclusion

No claim is currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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